1. 510(K) SUMMARY

Date Prepared: March 14, 2013

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COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

RS-3000

K121622

CLASSIFICATION INFORMATION

Classification Name:	Ophthalmoscope, A-C Powered
Medical Specialty:	Ophthalmic
Device Class:	II
Classification Panel:	Ophthalmic Device Panel
Product Codes:	OBO

PRODUCT CODE: CLASSIFICATION / CFR TITLE

OBO:	Class II § 21 CFR 886.1570

LEGALLY MARKETED PREDICATE DEVICE

Trade/Device Name:	RTVue with Normative Database
Applicant:	Optovue
510(k) Premarket Notification number:	K101505
Classification:	Class II
FDA Product Code:	HLI
Establishment Registration number:	3005950902

Trade/Device Name:	RTVue CAM with Corneal Power Measurement
Applicant:	Optovue
510(k) Premarket Notification number:	K111505
Classification:	Class II
FDA Product Code:	OBO, MMQ
Establishment Registration number:	3005950902

Trade/Device Name:	Cirrus HD-OCT with Retinal Nerve Fiber Layer and Macular Normative Database
Applicant:	Carl Zeiss
510(k) Premarket Notification number:	K083291
Classification:	Class II
FDA Product Code:	HLI
Establishment Registration number:	2918630

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GENERAL DEVICE DESCRIPTION

The Nidek Optical Coherence Tomography RS-3000, with Image Filing Software NAVIS-EX, is an ophthalmic instrument to observe and analyze the fundus, and the shape or the lesion of the retina in a non-contact and non-invasive manner. In addition, the anterior segment adapter attached over the objective lens of the main body enables non-invasive and non-contact observation of the shape of the anterior segment of the eye such as the cornea or anterior chamber angle. The image filing software NAVIS-EX permits management and various diagnoses of captured images. When the personal computer (PC) with the NAVIS-EX installed is connected to the RS-3000 through a cable, the image data acquired by the RS-3000 is transmitted. The software offers the functions such as filing, external I/F, image processing.

INDICATIONS FOR USE – RS-3000

The Nidek Optical Coherence Tomography RS-3000 including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

- the retina, retinal nerve fiber layer, and optic disc, and
- the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),

as an aid in the diagnosis and management of adults having or suspected of having ocular disease.

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DEVICE DESCRIPTION

Nidek Optical Coherence Tomography RS-3000, with Image Filing Software NAVIS-EX, is an ophthalmic instrument to observe and analyze the fundus, and the shape or the lesion of the retina in a non-contact and non-invasive manner. In addition, the anterior segment adapter attached over the objective lens of the main body enables non-invasive and non-contact observation of the shape of the anterior segment of the eye such as the cornea or anterior chamber angle.

By using confocal laser scanning ophthalmoscopy with a 785nm near-infrared light source, the fundus image (hereinafter referred to as SLO image) is obtained; and by optical coherence tomography with an 880 nm infrared light, the cross-sectional image of the fundus (hereinafter referred to as OCT image) is obtained.

The images captured using the RS-3000 allow observation of the fundus, and the shape, structure, and lesion of the patient's retina. In addition, the anterior segment adapter attached over the objective lens of the main body of the RS-3000 enables non-invasive and non-contact observation of the shape of the anterior segment of the eye such as the cornea or anterior chamber angle. The RS-3000 system is comprised of the following components: Main body, PC, PC monitor, Image Filing Software NAVIS-EX and isolation transformer. The NAVIS-EX software permits the management of various analyses of the captured images.

The image filing software NAVIS-EX permits management and various diagnoses of captured images. When the personal computer (PC) with the NAVIS-EX installed is connected to the RS-3000 through a cable, the image data acquired by the RS-3000 is transmitted. The software offers functions such as filing, external I/F, and image processing.

SUBSTANTIAL EQUIVALENCE

The Nidek Optical Coherence Tomography RS-3000, with Image Filing Software NAVIS-EX, is similar in technological characteristics, performance and has the same intended use as the predicate device(s). Any differences in technological characteristics between the Nidek Optical Coherence Tomography RS-3000 with Image Filing Software NAVIS-EX and the predicate device do not raise any new questions of safety or effectiveness. Thus, the RS-3000 with Image Filing Software NAVIS-EX is substantially equivalent to the predicate device(s).

COMPARISON TABLE OF TECHNOLOGICAL CHARACTERISTICS

Substantial Equivalence Comparison Table: RTVue		
Feature	**RS-3000 with NAVIS-EX**	**RTVue, CA**
Manufacturer	**NIDEK**	**Optovue**
510(k) Number	**K121622**	**K101505**
Classification	**886.1570**	**886.1570**
Product Code	**OBO**	**HLI**
Intended Use		
	The Nidek Optical Coherence Tomography RS-3000 including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of: **· the retina, retinal nerve fiber layer, and optic disc, and** **· the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),** **as an aid in the diagnosis and management of adults having or suspected of having ocular disease.**	**The RTVue with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal disease. The RTVue with Normative database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular disease.**
Performance Features		
Measurement principle		
Imaging of the Fundus/Anterior Segment	**Confocal scanning laser ophthalmoscopy for RS-3000**	**Near IR observation**
Tomographic Imaging of the Fundus/Anterior Segment	**Spectral Domain OCT**	**Spectral Domain OCT**
Scan rate (in OCT image capture)	**53,000 A-Scan/s**	**26,000 A-Scan/s**
Light source wavelength		
Imaging of the Fundus/Anterior Segment	**785 nm (Diode laser) for RS-3000,**	**735 nm (LED)**
Tomographic Imaging of the Fundus/Anterior Segment	**880 nm (SLD)**	**840 nm (SLD)**
Optical resolution		

Imaging of the Fundus	25 μm (in the X and Y directions) for RS-3000(SLO)	25 μm (in the X and Y directions)
Tomographic Imaging of the Fundus	20 μm (in the X and Y directions), 7 μm (in the Z direction)	15 μm (in the X and Y directions), 5 μm (in the Z direction)
Imaging of the Anterior Segment	50 μm (in the X and Y directions) for RS-3000(SLO)	70 μm (in the X and Y directions)
Tomographic Imaging of the Anterior Segment	20 μm (in the X and Y directions), 7 μm (in the Z direction)	15 μm (in the X and Y directions), 5 μm (in the Z direction)
Minimum pupil diameter required	φ2.5 mm	φ2.5mm
Focus range	−15 D to +10 D	−15 D to +20 D
Field of view		
Imaging of the Fundus	40°× 30 °for RS-3000,	32°×22°
Tomographic Imaging of the Fundus	Scan width: 3 mm to 9 mm Scan depth: 2.1 mm	Scan width: 2 mm to 12 mm Scan depth: 2 mm to 2.3 mm
Imaging of the Anterior Segment	14 mm×12 mm	5.75mm×4.3mm / 12mm×8mm
Tomographic Imaging of the Anterior Segment	Scan width: 2 mm to 8 mm Scan depth: 2.1 mm	Scan width: 1 mm to 3 mm / 2 mm to 6 mm Scan depth: 1.96 mm / 2.3 mm
Measurement and Analysis		
3D Volume Rendering	Yes	Yes
Retinal Thickness measurement (Total/Inner layer)	Yes	Yes
RNFL Thickness measurement	Yes	Yes
Optic Disc analysis	Yes	Yes
Pachymetry	Yes	Yes
Angle analysis	Yes	Yes

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Substantial Equivalence Comparison Table: Cirrus HD-OCT with Retinal Nerve Fiber Layer and Macular Normative Database		
Feature	**RS-3000 with NAVIS-EX**	**Cirrus HD-OCT**
Manufacturer	**NIDEK**	**Carl Zeiss**
510(k) Number	**K121622**	**K083291**
Classification	**886.1570**	**886.1570**
Product Code	**OBO**	**OBO**
Intended Use		
	The Nidek Optical Coherence Tomography RS-3000 including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of: **· the retina, retinal nerve fiber layer, and optic disc, and** **· the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),** **as an aid in the diagnosis and management of adults having or suspected of having ocular disease.**	**The Cirrus™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal fiber layer, macula, and optic disc. The Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL) and Macular Normative Database is a quantitative tool for the comparison of retinal nerve fiber layer and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.**
Performance Features		
Measurement principle	**Confocal scanning laser ophthalmoscopy**	**Confocal scanning laser ophthalmoscopy**
Light source wavelength	**785 nm (Diode laser)**	**750 nm (SLD)**
Optical power	**320μW**	**<1.5mW**
Frame rate	**10fps**	**>20Hz**
Field of view	**40°× 30°**	**36°× 30°**
Lateral resolution	**25 μm**	**25 μm**
Focus adjustment range	**−15D to+10D**	**−20D to+20D**
Detector type	**APD**	**Line CCD**
External fixation lamp	**Provided**	**Provided**
Anterior segment imaging	**Yes**	**Yes**

NON-CLINICAL PERFORMANCE SUMMARY

See ***Appendix 10*** and ***Appendix 11*** for supporting documentation regarding non-clinical performance testing.

The Nidek Optical Coherence Tomography RS-3000, with Image Filing Software NAVIS-EX, was evaluated according to the requirements of FDA recognized consensus standards (IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 62304, IEC 62366, ISO 15004-1, and ISO15004-2) and were found to meet the requirements of the applicable parts.

Bench testing of the repeatability and reproducibility of thickness measurement using the RS-3000 on a model eye was performed by multiple operators. Analysis of measurement errors in each result maintains sufficient accuracy with the device requirement specification of ± 5% accuracy of thickness measurements. As a result of this testing, the RS-3000 was found to maintain sufficient accuracy and to meet requirement specifications.

CLINICAL SUMMARY

A prospective clinical study was conducted at one clinical site located in the United States. A total of 89 subjects were enrolled to provide at least 80 evaluable eyes for the agreement measurements and at least 48 evaluable eyes for the precision and registration measurements.

The specific objectives of the study were to:

a. assess the agreement of the measurements of Total Retinal Thickness [ILM-RPE], Inner Retinal Thickness [ILM-IPL/INL], Outer Retinal Thickness [IPL/INL-RPE], Retinal Nerve Fiber Layer (RNFL) Thickness, Optic Disc Analysis and Central Corneal Thickness between the Nidek OCT RS-3000 and the Optovue RTVue1 predicate device;
b. compare the quality of the Anterior Chamber Angle OCT image between the Nidek RS-3000 and the Optovue RTVue predicate device;
c. assess the precision of the Nidek RS-3000 and the Optovue RTVue with respect to the measurements of Total Retinal Thickness [ILM-RPE], G Chart [NFL+GCL+IPL] Thickness (RS-3000 only), Inner Retinal Thickness [ILM-IPL/INL], Outer Retinal Thickness [IPL/INL-RPE], RNFL Thickness, Optic Disc Analysis and Central Corneal Thickness;
d. compare the precision of the Nidek RS-3000 to the precision of the Optovue RTVue;
e. obtain a quality assessment of the SLO image of the RS-3000; and
f. assess the registration function of the RS-3000.

The subject eye groups consisted of the following four groups: (1) Normal Eyes; (2) Eyes with Retinal Disease; (3) Eyes with Glaucoma and (4) Eyes with Corneal Disease (including eyes having undergone keratorefractive surgery). All study eyes were evaluated for the agreement and device capability assessments of this study. The first 12 eyes that had completed the study of each of the four study eye populations enrolled were evaluated for the precision assessment of the study. The first 12 eyes of the normal, retinal disease and glaucoma study eye groups that had completed the study were evaluated for the registration assessment. If both eyes of a subject were eligible for the study, one eye was selected randomly for evaluation. Both eyes of the normal eye study group must have met all normal eligibility criteria to participate in the study. The order of device testing was randomized.

Three Nidek RS-3000 devices and three Optovue RTVue devices were used. Each RS-3000 device was paired with one RTVue device for a total of three RS-3000/RTVue device pairs. Each of the three device pairs was designated one, and only one, operator for a total of three operator and device pairs for the precision and registration scans acquired for this study. Each operator and device pair was considered one configuration for a total of three

[1] The RTVue OCT is 510(k) cleared by the U.S. Food and Drug Administration and is commercially distributed in the United States; K101505.

specific operator/device configurations. Study eyes evaluated for precision and registration assessments were equally distributed among the three operator/device configurations.

Agreement Assessment: Twenty study eyes from each eye group that completed the study were included in the agreement assessment. The first acceptable RS-3000 scan with follow-up off and the first acceptable RTVue scan were designated as the agreement scans. Scans were acquired to capture the clinical data points for each of the agreement primary clinical endpoints.

Precision Assessment: The first 12 study eyes that completed the study from each eye population within the agreement assessment cohort were designated for the precision assessment. Each operator/device configuration tested four of the 12 study eyes for each eye group. Three measurements from each device were taken of each eye. This is a nested design with three configurations, four eyes per configuration and three measurements per device per eye. All three RS-3000 and RTVue scans had the registration feature disabled (follow-up off). Scans were acquired to capture the clinical data points for each of the precision primary clinical endpoints.

RS-3000 Registration Assessment: The same three specific operator/device configurations used in the precision assessment were used for the registration assessment of the RS-3000. The same 12 study eyes from each eye group for the precision assessment (excluding the corneal disease group as the RS-3000 does not have a registration feature associated with the pachymetry measurement) were designated for the registration assessment. The third acceptable scan obtained in the precision assessment was designated as the "baseline" scan. Three additional scans with the registration feature enabled (follow-up on) were acquired following the baseline scan. Scans were acquired to capture the clinical data points for each of the registration primary clinical endpoints.

Device Capability Assessment: All study eyes from each subject group were included for the SLO Quality Assessment. Utilizing the single scan acquired for the agreement assessment with the RS-3000 (only), the quality of the SLO image for each study eye was assessed by a Reading Center.

Safety Assessment: Safety endpoints were defined as any adverse events identified during the clinical study. There were zero adverse events that occurred during this clinical study.

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Clinical Endpoints:

	Data points	RS-3000 and RTVue	RS-3000 only	Agreement	Precision	Registration [RS-3000 only]
Total Retinal Thickness	9 segments	X		X	X	X
Inner Retinal Thickness	RS-3000: 8 segments RTVue: 9 segments	X		X	X	X
Outer Retinal Thickness	9 segments	X		X	X	X
RNFL	TSNI	X		X	X	X
G Chart	8 segments		X	X	X	X
Optic Disc Analysis	C/D Ratio, Disc Area, Cup Area	X		X	X	X
Pachymetry	Central Corneal Thickness	X		X		
Anterior Chamber Image	Image Assessment	X		X		
SLO Image	Image Assessment		X			

Scan Patterns and Scan Parameters:

	RS-3000 Scan Pattern : Parameter	RTVue Scan Pattern : Parameter
Total Retinal Thickness	Macular Map : 6 x 6mm	EMM5 Scan: 6 x 6mm
Inner Retinal Thickness		
Outer Retinal Thickness		
G Chart		
SLO Image		
RNFL	Disc Map :4.5 x 4.5mm	ONH Scan + 3D Disc Map : Radial Scans 3.45mm Circular Scans
Optic Disc Analysis		
Pachymetry	Corneal Radial : 6 x 6mm	Cam-L Pachymetry: 6mm Radial Scans with Circle
Anterior Chamber Image	ACA Line : 4mm	CS-HD Angle : 4mm

Acceptability of Scans:

Study technicians were instructed to acquire the minimum number of "acceptable" required scans for agreement and precision analysis as dictated in the clinical study protocol. Reasons for not accepting a scan included: Poor SSI (Signal Strength Index), Poor Patient Cooperation, Device Malfunction, Ocular Obstruction, Eye Blink, Eye Movement and Scan Pattern Cut Off and Other.

For the Total Retinal Thickness scans, there are 7.1%, 32.2% and 4.7% unacceptable scans for RS-3000 with follow-up off, RS-3000 with follow-up on and RTVue, respectively. The most common reasons for unacceptable scans are scan pattern (5.6%, RS-3000 with follow-up off), others (22.6%, RS-3000 with follow-up on), and eye blink and other (1.9% each, RTVue). Twenty-four of the 26 other reasons for RS-3000 with follow-up on were indicated as not aligning with baseline. The Inner and Outer Retinal Thickness scans had very similar unacceptable rates.

For the G-chart scans, there are 7.1% and 22.9% unacceptable scans for RS-3000 with follow-up off and on, respectively. The most common reasons for unacceptable scans are scan pattern (5.1%, RS-3000 with follow-up off) and others (16.2%, RS-3000 with follow-up on). Sixteen of the 17 other reasons for RS-3000 with follow-up on were indicated as not aligning with baseline.

For the RNFL and Optic Disc scans, there are 14.2%, 29.4% and 5.6% unacceptable scans for RS-3000 with follow-up off, RS-3000 with follow-up on and RTVue, respectively. The most common reasons for unacceptable scans are scan pattern (5%, RS-3000 with follow-up off) and others (16.8%, RS-3000 with follow-up on and 3.7%, RTVue). Eighteen of the 20 other reasons for RS-3000 with follow-up on were indicated as not aligning with baseline.

For the Central Corneal Thickness scans, there are 27.7% and 4.6% unacceptable scans for RS-3000 and RTVue, respectively. The most common reasons for unacceptable scans are scan pattern (4.1%, RS-3000), and poor SSI (1.9%, RTVue).

For the Anterior Chamber scans, there are 40.7% and 2.2% unacceptable scans for RS-3000 and RTVue, respectively. The most common reasons for unacceptable scans are poor patient cooperation (26%, RS-3000), and poor SSI and eye blink (1.1% each, RTVue).

The RS-3000 unacceptable scan rates were:

- lower in the normal group than the retinal group in retinal thickness scans (6% and 9.4% for follow-up off, and 20.4% and 40.9% for follow-up on),
- lower in the normal group than the glaucoma group in G-chart scans (2.5% and 10.3% for follow-up off, and 20.4% and 25% for follow-up on),
- lower in the normal group than the retinal group in RNFL scans (13% and 14.8% for follow-up off", and 20.4% and 37.3% for follow-up on),

- lower in the normal group than the glaucoma group and the corneal group in Central Corneal Thickness scans (23%, 32.6% and 26.2%, respectively), and
- similar among the four eye groups (from 37.1% to 44.7%) in Anterior Chamber scans.

Agreement Results:

Total Retinal Thickness

Limit of agreement analysis of the total retinal thickness is summarized in tables 1 through 4 below. For the normal subjects, the RS-3000 measured an average of 16.2, 19.0, 17.8, and 18.4μm greater than the RTVue in four segments (nasal 2, temporal 2, superior 2 and inferior 2, respectively). For the retinal group, all nine segments showed agreement between the two devices.

Inner Retinal Thickness

Limit of agreement analysis of the inner retinal thickness is summarized n tables 1 through 4 below. For the normal subjects, the RS-3000 measured an average of 20.0, 10.6, and 14.3μm less than the RTVue in three segments (temporal 1, superior 1, and inferior 1, respectively). For the retinal group, all eight segments showed agreement between the two devices.

Outer Retinal Thickness

Limit of agreement analysis of the total retinal thickness is summarized in tables 1 through 4 below. For the normal subjects, the RS-3000 measured an average of 14.7 to 34.3μm greater than the RTVue in all nine segments. For the retinal group, all but 1 segment showed agreement between the two devices. The RS-3000 measured an average of 21.3μm greater than the RTVue in the temporal segment 1.

Retinal Nerve Fiber Layer Thickness

Limit of agreement analysis of the retinal nerve fiber layer is summarized in tables 1 through 4 below. For all subjects, in both the normal and glaucoma study groups, the RS-3000 showed agreement with the RTVue in all four quadrants and in the total mean.

Optic Disc Analysis

Limit of agreement analysis of the optic disc analysis is summarized in tables 1 through 4 below. For all subjects, in both the normal and glaucoma study groups, the RS-3000 showed agreement with the RTVue in all four parameters analyzed, C/D horizontal, C/D vertical, Disc area and Cup area.

Central Corneal Thickness

The RS-3000 measured an average of 13.4μm higher than the RTVue for the measurement of central corneal thickness for the normal study group. In the corneal group, no significant differences in the measurement of central corneal thickness were found between the two devices.

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Table 1: Mean Difference in Retinal Thickness, RNFL, Optic Disc and Central Corneal Thickness Between RS-3000 and RTVue Subjects With Normal Eyes

	n	RS-3000 Mean (SD)	RTVue Mean (SD)	Difference Mean (SD)[1]	95% CI for Mean Difference[2]	95% LOA for Mean Difference[3]
Total Retinal Thickness (µm)						
Nasal 1	20	307.9 (19.4)	299.7 (22.0)	8.2 (9.4)	3.8, 12.6	-10.5, 26.9
Nasal 2	20	338.2 (19.2)	322.0 (19.2)	16.2 (6.1)	13.3, 19.0	3.9, 28.4
Center	20	266.9 (22.9)	266.8 (21.9)	0.1 (7.9)	-3.6, 3.8	-15.6, 15.8
Temporal 1	20	282.3 (17.0)	280.0 (18.0)	2.4 (11.9)	-3.2, 7.9	-21.4, 26.1
Temporal 2	20	322.6 (16.0)	303.6 (18.8)	19.0 (9.3)	14.6, 23.3	0.4, 37.5
Superior 1	20	295.6 (19.8)	282.3 (19.6)	13.4 (9.1)	9.1, 17.6	-4.8, 31.5
Superior 2	20	336.0 (19.3)	318.2 (17.3)	17.8 (7.2)	14.4, 21.2	3.3, 32.3
Inferior 1	20	284.4 (16.6)	283.7 (18.0)	0.7 (8.0)	-3.1, 4.5	-15.4, 16.8
Inferior 2	20	333.6 (17.4)	315.2 (17.2)	18.4 (8.2)	14.5, 22.3	1.9, 34.9
Inner Retinal Thickness (µm)						
Nasal 1	20	111.5 (10.5)	120.1 (12.2)	-8.7 (8.9)	-12.8, -4.5	-26.4, 9.1
Nasal 2	20	112.3 (8.4)	130.6 (13.6)	-18.3 (11.5)	-23.7, -12.9	-41.2, 4.6
Temporal 1	20	86.6 (8.5)	106.6 (8.4)	-20.0 (5.9)	-22.8, -17.2	-31.9, -8.1
Temporal 2	20	102.4 (6.1)	114.1 (10.3)	-11.7 (8.3)	-15.5, -7.8	-28.2, 4.9
Superior 1	20	97.5 (9.6)	108.0 (8.4)	-10.6 (4.9)	-12.9, -8.2	-20.4, -0.7
Superior 2	20	114.2 (9.3)	127.2 (12.3)	-13.0 (12.0)	-18.6, -7.4	-37.0, 11.0
Inferior 1	20	97.0 (8.3)	111.3 (9.4)	-14.3 (6.5)	-17.4, -11.2	-27.4, -1.2
Inferior 2	20	115.1 (8.5)	125.8 (10.3)	-10.8 (7.6)	-14.3, -7.2	-26.0, 4.5
Outer Retinal Thickness (µm)						
Nasal 1	20	195.8 (11.6)	179.6 (13.8)	16.3 (7.0)	13.0, 19.5	2.2, 30.3
Nasal 2	20	225.4 (12.5)	191.2 (15.1)	34.3 (9.7)	29.7, 38.8	14.8, 53.7
Center	20	218.4 (15.3)	185.2 (11.7)	33.2 (7.0)	29.9, 36.5	19.2, 47.2
Temporal 1	20	195.5 (10.5)	173.3 (12.6)	22.2 (7.8)	18.5, 25.8	6.5, 37.8
Temporal 2	20	219.7 (11.0)	189.5 (14.0)	30.2 (8.6)	26.1, 34.2	12.9, 47.4
Superior 1	20	197.5 (11.7)	174.1 (13.5)	23.5 (8.6)	19.4, 27.5	6.3, 40.6
Superior 2	20	221.0 (12.5)	191.0 (16.4)	30.1 (11.9)	24.5, 35.6	6.2, 53.9
Inferior 1	20	186.9 (10.7)	172.2 (11.4)	14.7 (4.3)	12.7, 16.7	6.2, 23.2
Inferior 2	20	218.0 (12.4)	189.8 (14.0)	28.2 (7.1)	24.9, 31.5	14.0, 42.4
Retinal Nerve Fiber Layer Thickness (µm)						
Superior	20	125.5 (16.5)	116.8 (12.6)	8.7 (10.7)	3.7, 13.7	-12.7, 30.1
Temporal	20	63.2 (11.3)	76.4 (8.5)	-13.2 (9.1)	-17.5, -9.0	-31.4, 5.0
Inferior	20	128.0 (14.3)	127.4 (11.7)	0.5 (7.1)	-2.8, 3.8	-13.7, 14.7

	n	RS-3000 Mean (SD)	RTVue Mean (SD)	Difference Mean (SD) [1]	95% CI for Mean Difference[2]	95% LOA for Mean Difference[3]
Nasal	20	84.1 (11.9)	81.1 (8.7)	3.0 (8.6)	-1.0, 7.0	-14.2, 20.2
Total Mean	20	101.0 (10.3)	100.4 (7.8)	0.5 (4.6)	-1.6, 2.7	-8.6, 9.7
Optic Disc						
C/D Horizontal	19	0.542 (0.148)	0.687 (0.205)	-0.176 (0.124)	-0.236, -0.116	-0.425, 0.072
C/D Vertical	19	0.495 (0.128)	0.585 (0.166)	-0.111 (0.071)	-0.145, -0.077	-0.253, 0.031
Disc Area (mm^2)	20	2.134 (0.396)	1.849 (0.339)	0.285 (0.290)	0.150, 0.420	-0.294, 0.864
Cup Area (mm^2)	19	0.643 (0.383)	0.712 (0.515)	-0.106 (0.248)	-0.225, 0.014	-0.601, 0.389
Central Corneal Thickness (µm)						
	20	543.2 (28.5)	529.8 (29.2)	13.4 (6.6)	10.3, 16.4	0.2, 26.5

Data included are the first accepted scans from RS-3000 with follow-up off and the first accepted scans from RTVue.

1 Difference = RS-3000 – RTVue

2 95% confidence interval for mean difference based on t-distribution

3 95% limits of agreement = mean difference +/- 2 x difference SD

Program: LOA.sas (11DEC2012 20:56:34)

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Table 2: Mean Difference in Retinal Thickness Between RS-3000 and RTVue Subjects With Retinal Disease

	n	RS-3000 Mean (SD)	RTVue Mean (SD)	Difference Mean (SD)[1]	95% CI for Mean Difference[2]	95% LOA for Mean Difference[3]
Total Retinal Thickness (µm)						
Nasal 1	20	309.2 (31.9)	296.8 (36.1)	12.4 (18.7)	3.6, 21.2	-25.1, 49.9
Nasal 2	20	327.8 (48.1)	317.4 (47.8)	10.4 (12.7)	4.4, 16.4	-15.1, 35.9
Center	20	280.1 (76.0)	277.0 (70.1)	3.1 (14.8)	-3.8, 10.0	-26.6, 32.8
Temporal 1	20	275.0 (19.9)	269.5 (24.6)	5.6 (9.6)	1.0, 10.1	-13.7, 24.8
Temporal 2	20	308.9 (46.2)	290.3 (45.3)	18.6 (9.4)	14.1, 23.0	-0.3, 37.4
Superior 1	20	290.6 (28.3)	279.8 (31.9)	10.8 (9.0)	6.5, 15.0	-7.2, 28.7
Superior 2	20	323.0 (47.2)	309.2 (46.2)	13.8 (10.2)	9.0, 18.6	-6.6, 34.2
Inferior 1	20	287.4 (30.7)	284.1 (37.3)	3.3 (10.3)	-1.5, 8.1	-17.2, 23.8
Inferior 2	20	327.9 (48.1)	315.0 (52.0)	13.0 (8.1)	9.1, 16.8	-3.3, 29.2
Inner Retinal Thickness (µm)						
Nasal 1	20	114.8 (20.9)	115.6 (19.5)	-0.9 (14.7)	-7.7, 6.0	-30.2, 28.5
Nasal 2	20	110.7 (31.3)	124.6 (26.9)	-14.0 (18.1)	-22.4, -5.5	-50.1, 22.2
Temporal 1	20	86.4 (12.0)	102.9 (13.3)	-16.5 (9.3)	-20.8, -12.1	-35.0, 2.1
Temporal 2	20	103.6 (19.0)	109.6 (20.1)	-6.0 (13.8)	-12.4, 0.4	-33.5, 21.5
Superior 1	20	100.2 (18.1)	107.0 (16.3)	-6.9 (8.2)	-10.7, -3.0	-23.2, 9.5
Superior 2	20	111.5 (27.1)	119.6 (21.4)	-8.2 (15.4)	-15.3, -1.0	-38.9, 22.6
Inferior 1	20	100.8 (21.2)	109.3 (13.9)	-8.5 (14.0)	-15.0, -1.9	-36.5, 19.6
Inferior 2	20	120.0 (21.6)	120.6 (21.7)	-0.6 (15.2)	-7.7, 6.6	-31.0, 29.9
Outer Retinal Thickness (µm)						
Nasal 1	20	194.0 (15.3)	181.2 (20.7)	12.8 (16.6)	5.0, 20.5	-20.5, 46.0
Nasal 2	20	216.8 (25.1)	192.7 (25.3)	24.1 (19.4)	15.0, 33.2	-14.6, 62.8
Center	20	210.9 (41.0)	190.6 (53.5)	20.4 (23.9)	9.2, 31.5	-27.4, 68.1
Temporal 1	20	188.0 (13.9)	166.7 (13.0)	21.3 (9.5)	16.9, 25.7	2.4, 40.2
Temporal 2	20	204.8 (32.5)	180.7 (27.9)	24.1 (13.9)	17.6, 30.6	-3.7, 51.9
Superior 1	20	189.8 (14.5)	172.7 (16.9)	17.2 (11.6)	11.7, 22.6	-6.0, 40.3
Superior 2	20	210.9 (28.1)	189.6 (28.8)	21.4 (19.0)	12.5, 30.2	-16.7, 59.4
Inferior 1	20	185.9 (11.5)	174.9 (25.6)	11.0 (16.5)	3.3, 18.7	-22.1, 44.1
Inferior 2	20	207.3 (28.9)	194.3 (34.9)	13.0 (14.9)	6.0, 19.9	-16.8, 42.7

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n	RS-3000 Mean (SD)	RTVue Mean (SD)	Difference Mean (SD) [1]	95% CI for Mean Difference [2]	95% LOA for Mean Difference [3]

Data included are the first accepted scans from RS-3000 with follow-up off and the first accepted scans from RTVue.

1 Difference = RS-3000 – RTVue

2 95% confidence interval for mean difference based on t-distribution

3 95% limits of agreement = mean difference +/- 2 x difference SD

Program: LOA.sas (11DEC2012 20:56:34)

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Table 3: Mean Difference in RNFL and Optic Disc Between RS-3000 and RTVue Subjects With Glaucoma

	n	RS-3000 Mean (SD)	RTVue Mean (SD)	Difference Mean (SD)[1]	95% CI for Mean Difference[2]	95% LOA for Mean Difference[3]
Retinal Nerve Fiber Layer Thickness (µm)						
Superior	20	90.9 (26.0)	86.3 (19.4)	4.5 (9.3)	0.2, 8.9	-14.0, 23.1
Temporal	20	53.1 (14.0)	65.8 (13.6)	-12.8 (9.7)	-17.3, -8.2	-32.2, 6.6
Inferior	20	85.9 (27.4)	91.4 (24.3)	-5.5 (8.3)	-9.4, -1.6	-22.0, 11.0
Nasal	20	70.0 (22.8)	66.1 (10.2)	3.9 (18.3)	-4.7, 12.5	-32.8, 40.6
Total Mean	20	75.7 (16.1)	77.4 (13.5)	-1.8 (6.0)	-4.6, 1.1	-13.8, 10.3
Optic Disc						
C/D Horizontal	20	0.783 (0.130)	0.917 (0.129)	-0.134 (0.117)	-0.189, -0.079	-0.368, 0.100
C/D Vertical	20	0.762 (0.119)	0.834 (0.133)	-0.073 (0.065)	-0.103, -0.042	-0.202, 0.057
Disc Area (mm^2)	20	2.195 (0.385)	2.028 (0.362)	0.167 (0.332)	0.012, 0.322	-0.497, 0.831
Cup Area (mm^2)	20	1.305 (0.443)	1.434 (0.539)	-0.130 (0.394)	-0.314, 0.055	-0.917, 0.658

Data included are the first accepted scans from RS-3000 with follow-up off and the first accepted scans from RTVue.
1 Difference = RS-3000 – RTVue
2 95% confidence interval for mean difference based on t-distribution
3 95% limits of agreement = mean difference +/- 2 x difference SD

Program: LOA.sas (11DEC2012 20:56:34)

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Table 4: Mean Difference in Central Corneal Thickness Between RS-3000 and RTVue Subjects With Corneal Disease

	n	RS-3000 Mean (SD)	RTVue Mean (SD)	Difference Mean (SD)[1]	95% CI for Mean Difference[2]	95% LOA for Mean Difference[3]
Central Corneal Thickness (µm)						
	20	520.8 (63.8)	508.1 (63.2)	12.8 (8.0)	9.0, 16.5	-3.2, 28.7

Data included are the first accepted scans from RS-3000 with follow-up off and the first accepted scans from RTVue.
1 Difference = RS-3000 – RTVue
2 95% confidence interval for mean difference based on t-distribution
3 95% limits of agreement = mean difference +/- 2 x difference SD

Program: LOA.sas (11DEC2012 20:56:34)

Precision Results:

Total Retinal Thickness

Repeatability and reproducibility of the total retinal thickness are summarized in tables 5 through 11 below.

For the normal group, the repeatability limits (range: 2.8 to 7.393µm) and the reproducibility limits (range: 2.8 to 7.393µm) of RS-3000 with follow-up off tended to be smaller than or similar to that of the RTVue (the repeatability limits and the reproducibility limits of RTVue have the same range: 6.313 to 17.746µm). The repeatability limits and the reproducibility limits were similar between the two settings of RS-3000 (the repeatability limits and the reproducibility limits of RS-3000 On have the same range: 2.761 to 6.55µm).

For the retinal group, the repeatability limits of RS-3000 with follow-up off (range: 6.049 to 32.453µm) tended to be larger than or similar to that of the RTVue (range: 5.522 to 17.511µm). However, there was no clear pattern in the reproducibility limits between the two study devices (range: 6.049 to 32.453µm for RS-3000 Off, 6.031 to 17.511µm for RTVue). The repeatability limits and the reproducibility limits were similar between the two settings of RS-3000 (the repeatability limits and the reproducibility limits of RS-3000 On have the same range: 4.62 to 27.403µm).

Inner Retinal Thickness

Repeatability and reproducibility of the inner retinal thickness are summarized in tables 5 through 11 below.

For the normal group, the repeatability limits (range: 1.476 to 5.442µm) and the reproducibility limits (range: 1.476 to 5.442µm) of RS-3000 with follow-up off tended to be smaller than or similar to that of the RTVue (repeatability limit range: 3.461 to 10.601µm; reproducibility limit range: 3.461 to 11.843µm). The repeatability limits and the reproducibility limits were similar between the two settings of RS-3000 (the repeatability limits and the reproducibility limits of RS-3000 On have the same range: 2.034 to 5.280µm).

For the retinal group, the repeatability limits (range: 5.176 to 14.162µm) and the reproducibility limits (range: 5.176 to 14.162µm) of RS-3000 with follow-up off tended to be smaller than or similar to that of the RTVue (repeatability limit range: 6.433 to 18.397µm; reproducibility limit range: 8.056 to 20.9µm). The repeatability limits and the reproducibility limits of RS-3000 with follow-up off tended to be larger or similar to that of the RS-3000 with follow-up on (the repeatability limits and the reproducibility limits of RS-3000 On have the same range: 3.365 to 18.026µm).

Outer Retinal Thickness
Repeatability and reproducibility of the outer retinal thickness are summarized in tables 5 through 11 below

For the normal group, the repeatability limits (range: 2.425 to 4.174µm) and the reproducibility limits (range: 2.425 to 5.032µm) of RS-3000 with follow-up off tended to be smaller than that of the RTVue (the repeatability limits and the reproducibility limits of RTVue have the same range: 7.961 to 12.531µm) in all segments. The repeatability limits and the reproducibility limits were similar between the two settings of RS-3000 (the repeatability limits and the reproducibility limits of RS-3000 On have the same range: 2.139 to 4.252µm).

For the retinal group, the repeatability limits of RS-3000 with follow-up off (range: 4.961 to 23.653µm) tended to be smaller than or similar to that of the RTVue (range: 7.865 to 20.293µm). The reproducibility limits of RS-3000 with follow-up off (range: 4.961 to 25.459µm) tended to be smaller in the superior and inferior segments than that of RTVue (range: 7.865 to 20.293µm), and there was no clear pattern in the other segments. The repeatability limits and the reproducibility limits of RS-3000 with follow-up off tended to be larger than or similar to that of the RS-3000 with follow-up on (repeatability range: 3.30 to 16.755µm and reproducibility range: 3.30 to 23.312µm).

G Chart
Repeatability and reproducibility of the G-chart thickness are summarized in table 5 through 11 below.

For the normal group, the repeatability and reproducibility limits were similar in all but 2 segments between the 2 settings of RS-3000 (repeatability limit range: 1.807 to 6.209µm for the off setting and 1.807 to 4.501µm for the on setting; the reproducibility limits had the same range as the repeatability limits). The repeatability and reproducibility limits of the 2 inferior/temporal segments were greater in the off setting than the on setting.

For the glaucoma group, the repeatability and reproducibility limits of the off setting tended to be greater than or similar to that of the on setting (repeatability limit range: 3.333 to 16.858µm for the off setting and 1.924 to 19.281µm for the on setting; reproducibility limit range: 6.616 to 28.245µm for the off setting and 1.924 to 29.736µm for the on setting).

Retinal Nerve Fiber Layer
Repeatability and reproducibility of the retinal nerve fiber layer thickness are summarized in tables 5 through 11 below.

For the normal group, the repeatability limits (range: 6.682 to 20.661µm) and the reproducibility limits (range: 6.682 to 21.575µm) of RS-3000 with follow-up off tended to be larger than that of the RTVue (the repeatability limit range: 3.508 to 8.516µm; the reproducibility limit range: 3.508 to 14.148µm). The repeatability limits and the reproducibility limits were similar between the two settings of RS-3000 (the repeatability limits and the reproducibility limits of RS-3000 On have the same range: 8.043 to 16.413µm)

For the glaucoma group, the repeatability limits of RS-3000 with follow-up off (range: 11.122 to 32.506µm) tended to be larger than that of the RTVue (range: 3.67 to 10.291µm). The repeatability limits of the off setting were greater than or similar to the on setting (range: 7.525 to 20.766µm). However, there is no clear pattern in the reproducibility limits between the RS-3000 with follow-up off (range: 15.591 to 46.568µm) and RTVue (range: 6.533 to 26.092µm). The reproducibility limits were similar between the two settings of RS-3000 (range of the on setting: 10.139 to 52.57µm).

Optic Disc Analysis

Repeatability and reproducibility of the optic disc are summarized in tables 5 through 11 below.

For the normal group, the repeatability limits of RS-3000 with follow-up off (range: 0.058 to 0.478µm) tended to be larger in C/D horizontal, disc area and cup area, and smaller in C/D vertical than that of the RTVue (range: 0.073 to 0.196µm). The reproducibility limits were similar between RS-3000 with follow-up off (range: 0.241 to 1.029µm) and RTVue (range: 0.238 to 1.039µm), except for disc area in which the RS-3000 with follow-up off tended to be larger. The repeatability limits (range of on setting: 0.065 to 0.388µm) and the reproducibility limits (range of on setting: 0.211 to 1.092µm) were similar between the two settings of RS-3000, except for C/D horizontal in which the repeatability limit of the off setting tended to be larger than that of the on setting.

For the glaucoma group, the repeatability limits of RS-3000 with follow-up off (range: 0.087 to 0.318µm) tended to be smaller in C/D horizontal and larger in disc area than that of the RTVue (range: 0.117 to 0.413µm). The two devices had similar repeatability limits in C/D vertical and cup area. The reproducibility limits of RS-3000 with follow-up off (range: 0.087 to 0.775µm) tended to be smaller in C/D horizontal, C/D vertical and cup area, and larger in disc area than that of RTVue (range: 0.186 to 0.455µm). The repeatability and reproducibility limits of the off setting were smaller than or similar to the on setting (repeatability limit range: 0.132 to 0.422µm; reproducibility limit range: 0.132 to 0.918µm).

Central Corneal Thickness

The repeatability limits of RS-3000 were larger than that of the RTVue in both the normal (8.15µm and 3.024µm, respectively) and corneal groups (18.933µm and 3.199µm, respectively). The reproducibility limit of RS-3000 was larger than that of the RTVue in the normal group (31.336µm and 3.024µm, respectively), but similar between the two devices in the corneal group (57.874µm and 53.963µm, respectively).

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Table 5: RS-3000 with Follow-up Off: Repeatability and Reproducibility in Measuring Retinal Thickness, G-Chart Thickness, RNFL, Optic Disc and Central Corneal Thickness Subjects With Normal Eyes

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Total Retinal Thickness (µm)							
Nasal 1	12	1.642	4.596	1.642	4.596	0.531	0.531
Nasal 2	12	1.537	4.302	1.537	4.302	0.450	0.450
Center	12	2.641	7.393	2.641	7.393	0.992	0.992
Temporal 1	12	2.115	5.921	2.115	5.921	0.746	0.746
Temporal 2	12	1.000	2.800	1.000	2.800	0.309	0.309
Superior 1	12	1.354	3.791	1.354	3.791	0.459	0.459
Superior 2	12	1.518	4.252	1.518	4.252	0.448	0.448
Inferior 1	12	2.230	6.244	2.230	6.244	0.781	0.781
Inferior 2	12	1.344	3.762	1.344	3.762	0.401	0.401
Inner Retinal Thickness (µm)							
Nasal 1	12	0.898	2.513	0.898	2.513	0.798	0.798
Nasal 2	12	1.700	4.759	1.700	4.759	1.481	1.481
Temporal 1	12	1.394	3.905	1.394	3.905	1.599	1.599
Temporal 2	12	1.179	3.300	1.179	3.300	1.150	1.150
Superior 1	12	0.527	1.476	0.527	1.476	0.540	0.540
Superior 2	12	1.564	4.378	1.564	4.378	1.341	1.341
Inferior 1	12	1.179	3.300	1.179	3.300	1.211	1.211
Inferior 2	12	1.944	5.442	1.944	5.442	1.681	1.681
Outer Retinal Thickness (µm)							
Nasal 1	12	1.130	3.165	1.130	3.165	0.577	0.577
Nasal 2	12	0.898	2.513	0.898	2.513	0.397	0.397
Center	12	1.434	4.015	1.434	4.015	0.655	0.655
Temporal 1	12	0.866	2.425	0.866	2.425	0.442	0.442
Temporal 2	12	1.054	2.952	1.054	2.952	0.478	0.478
Superior 1	12	0.866	2.425	0.866	2.425	0.440	0.440
Superior 2	12	1.027	2.877	1.027	2.877	0.464	0.464
Inferior 1	12	1.106	3.096	1.797	5.032	0.589	0.957
Inferior 2	12	1.491	4.174	1.491	4.174	0.681	0.681
G Chart Thickness (µm)							
Superior/Nasal 1	12	0.646	1.807	0.646	1.807	0.598	0.598

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Superior/Nasal 2	12	1.958	5.482	1.958	5.482	1.673	1.673
Superior/Temporal 1	12	0.957	2.681	0.957	2.681	1.085	1.085
Superior/Temporal 2	12	1.555	4.353	1.555	4.353	1.432	1.432
Inferior/Nasal 1	12	0.898	2.513	0.898	2.513	0.836	0.836
Inferior/Nasal 2	12	1.667	4.667	1.667	4.667	1.449	1.449
Inferior/Temporal 1	12	1.528	4.277	1.528	4.277	1.676	1.676
Inferior/Temporal 2	12	2.217	6.209	2.217	6.209	2.034	2.034
Retinal Nerve Fiber Layer Thickness (µm)							
Superior	12	7.379	20.661	7.379	20.661	5.746	5.746
Temporal	12	4.381	12.267	4.381	12.267	7.070	7.070
Inferior	12	4.014	11.239	4.014	11.239	3.055	3.055
Nasal	12	6.593	18.461	7.705	21.575	8.063	9.422
Total Mean	12	2.386	6.682	2.386	6.682	2.347	2.347
Optic Disc							
C/D Horizontal	12	0.050	0.141	0.123	0.344	9.302	22.701
C/D Vertical	12	0.021	0.058	0.086	0.241	4.184	17.325
Disc Area (mm^2)	12	0.171	0.478	0.365	1.023	7.598	16.251
Cup Area (mm^2)	12	0.055	0.155	0.368	1.029	8.112	53.949
Central Corneal Thickness (µm)							
	12	2.911	8.150	11.191	31.336	0.529	2.035

All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

Program: RR.sas (11DEC2012 20:58:33)

Table 6: RS-3000 with Follow-up On: Repeatability and Reproducibility in Measuring Retinal Thickness, G-Chart Thickness, RNFL and Optic Disc Subjects With Normal Eyes

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Total Retinal Thickness (µm)							
Nasal 1	12	1.787	5.005	1.787	5.005	0.578	0.578
Nasal 2	12	1.434	4.014	1.434	4.014	0.420	0.420
Center	12	2.339	6.550	2.339	6.550	0.872	0.872
Temporal 1	12	1.658	4.643	1.658	4.643	0.583	0.583
Temporal 2	12	1.641	4.596	1.641	4.596	0.507	0.507
Superior 1	12	1.143	3.199	1.143	3.199	0.388	0.388
Superior 2	12	1.354	3.791	1.354	3.791	0.400	0.400
Inferior 1	12	1.764	4.939	1.764	4.939	0.615	0.615
Inferior 2	12	0.986	2.761	0.986	2.761	0.294	0.294
Inner Retinal Thickness (µm)							
Nasal 1	12	0.727	2.034	0.727	2.034	0.643	0.643
Nasal 2	12	1.886	5.280	1.886	5.280	1.634	1.634
Temporal 1	12	1.054	2.952	1.054	2.952	1.205	1.205
Temporal 2	12	1.106	3.096	1.106	3.096	1.077	1.077
Superior 1	12	0.745	2.087	0.745	2.087	0.763	0.763
Superior 2	12	1.344	3.763	1.344	3.763	1.148	1.148
Inferior 1	12	0.913	2.556	0.913	2.556	0.935	0.935
Inferior 2	12	1.333	3.733	1.333	3.733	1.160	1.160
Outer Retinal Thickness (µm)							
Nasal 1	12	1.518	4.252	1.518	4.252	0.776	0.776
Nasal 2	12	0.943	2.640	0.943	2.640	0.418	0.418
Center	12	1.225	3.429	1.225	3.429	0.558	0.558
Temporal 1	12	0.882	2.469	0.882	2.469	0.449	0.449
Temporal 2	12	1.093	3.060	1.093	3.060	0.495	0.495
Superior 1	12	0.764	2.139	0.764	2.139	0.388	0.388
Superior 2	12	1.080	3.024	1.080	3.024	0.488	0.488
Inferior 1	12	1.202	3.365	1.202	3.365	0.637	0.637
Inferior 2	12	1.118	3.130	1.118	3.130	0.510	0.510
G Chart Thickness (µm)							
Superior/Nasal 1	12	0.646	1.807	0.646	1.807	0.596	0.596

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Superior/Nasal 2	12	1.581	4.427	1.581	4.427	1.343	1.343
Superior/Temporal 1	12	1.000	2.800	1.000	2.800	1.130	1.130
Superior/Temporal 2	12	1.118	3.130	1.118	3.130	1.023	1.023
Inferior/Nasal 1	12	0.799	2.238	0.799	2.238	0.743	0.743
Inferior/Nasal 2	12	1.607	4.501	1.607	4.501	1.400	1.400
Inferior/Temporal 1	12	0.882	2.469	0.882	2.469	0.963	0.963
Inferior/Temporal 2	12	1.213	3.397	1.213	3.397	1.119	1.119
Retinal Nerve Fiber Layer Thickness (µm)							
Superior	12	5.862	16.413	5.862	16.413	4.578	4.578
Temporal	12	3.508	9.822	3.508	9.822	5.529	5.529
Inferior	12	4.696	13.150	4.696	13.150	3.604	3.604
Nasal	12	5.006	14.017	5.006	14.017	6.268	6.268
Total Mean	12	2.872	8.043	2.872	8.043	2.835	2.835
Optic Disc							
C/D Horizontal	12	0.035	0.097	0.096	0.270	6.674	18.511
C/D Vertical	12	0.023	0.065	0.075	0.211	4.738	15.328
Disc Area (mm^2)	12	0.138	0.388	0.390	1.092	6.220	17.527
Cup Area (mm^2)	12	0.059	0.164	0.322	0.902	9.151	50.283

All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

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Table 7: RS-3000 with Follow-up Off: Repeatability and Reproducibility in Measuring Retinal Thickness
Subjects With Retinal Disease

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Total Retinal Thickness (µm)							
Nasal 1	12	10.127	28.356	10.127	28.356	3.233	3.233
Nasal 2	12	7.145	20.007	7.145	20.007	2.144	2.144
Center	12	4.106	11.497	4.106	11.497	1.391	1.391
Temporal 1	12	11.590	32.453	11.590	32.453	4.151	4.151
Temporal 2	12	2.708	7.583	2.708	7.583	0.846	0.846
Superior 1	12	2.160	6.049	2.160	6.049	0.732	0.732
Superior 2	12	3.232	9.049	3.232	9.049	0.957	0.957
Inferior 1	12	2.698	7.554	2.698	7.554	0.940	0.940
Inferior 2	12	3.253	9.109	3.253	9.109	0.977	0.977
Inner Retinal Thickness (µm)							
Nasal 1	12	5.058	14.162	5.058	14.162	4.331	4.331
Nasal 2	12	4.857	13.598	4.857	13.598	4.303	4.303
Temporal 1	12	3.375	9.449	3.375	9.449	3.757	3.757
Temporal 2	12	3.041	8.516	3.041	8.516	2.807	2.807
Superior 1	12	2.021	5.658	2.021	5.658	1.934	1.934
Superior 2	12	3.460	9.688	3.460	9.688	2.949	2.949
Inferior 1	12	1.849	5.176	1.849	5.176	1.823	1.823
Inferior 2	12	2.934	8.217	2.934	8.217	2.392	2.392
Outer Retinal Thickness (µm)							
Nasal 1	12	7.165	20.061	7.165	20.061	3.657	3.657
Nasal 2	12	7.057	19.760	9.093	25.459	3.209	4.134
Center	12	4.113	11.517	4.113	11.517	1.843	1.843
Temporal 1	12	8.448	23.653	8.448	23.653	4.470	4.470
Temporal 2	12	4.010	11.229	4.010	11.229	1.898	1.898
Superior 1	12	1.772	4.961	1.772	4.961	0.933	0.933
Superior 2	12	2.949	8.256	2.949	8.256	1.343	1.343
Inferior 1	12	1.871	5.239	1.871	5.239	1.011	1.011
Inferior 2	12	3.167	8.867	3.167	8.867	1.510	1.510

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility

All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

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Table 8: RS-3000 with Follow-up On: Repeatability and Reproducibility in Measuring Retinal Thickness
Subjects With Retinal Disease

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Total Retinal Thickness (µm)							
Nasal 1	12	5.984	16.755	5.984	16.755	1.907	1.907
Nasal 2	12	8.033	22.492	8.033	22.492	2.399	2.399
Center	12	5.250	14.699	5.250	14.699	1.767	1.767
Temporal 1	12	9.787	27.403	9.787	27.403	3.508	3.508
Temporal 2	12	2.774	7.767	2.774	7.767	0.868	0.868
Superior 1	12	1.650	4.620	1.650	4.620	0.558	0.558
Superior 2	12	2.455	6.874	2.455	6.874	0.722	0.722
Inferior 1	12	2.533	7.093	2.533	7.093	0.882	0.882
Inferior 2	12	2.088	5.847	2.088	5.847	0.632	0.632
Inner Retinal Thickness (µm)							
Nasal 1	12	1.202	3.365	1.202	3.365	1.031	1.031
Nasal 2	12	6.438	18.026	6.438	18.026	5.654	5.654
Temporal 1	12	4.580	12.823	4.580	12.823	5.122	5.122
Temporal 2	12	2.764	7.739	2.764	7.739	2.555	2.555
Superior 1	12	1.667	4.667	1.667	4.667	1.583	1.583
Superior 2	12	1.443	4.042	1.443	4.042	1.217	1.217
Inferior 1	12	2.211	6.191	2.211	6.191	2.168	2.168
Inferior 2	12	1.555	4.353	1.555	4.353	1.284	1.284
Outer Retinal Thickness (µm)							
Nasal 1	12	5.984	16.755	8.326	23.312	3.040	4.230
Nasal 2	12	4.890	13.693	5.412	15.153	2.218	2.455
Center	12	3.136	8.780	3.136	8.780	1.405	1.405
Temporal 1	12	5.354	14.992	5.354	14.992	2.834	2.834
Temporal 2	12	3.100	8.681	3.100	8.681	1.469	1.469
Superior 1	12	1.247	3.492	1.247	3.492	0.657	0.657
Superior 2	12	2.603	7.290	2.603	7.290	1.180	1.180
Inferior 1	12	1.179	3.300	1.179	3.300	0.638	0.638
Inferior 2	12	2.345	6.567	2.345	6.567	1.122	1.122

All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

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Table 9: RS-3000 with Follow-up Off: Repeatability and Reproducibility in Measuring G-Chart Thickness, RNFL and Optic Disc
Subjects With Glaucoma

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
G Chart Thickness (µm)							
Superior/Nasal 1	12	1.258	3.523	10.088	28.245	1.456	11.673
Superior/Nasal 2	12	2.517	7.047	2.517	7.047	2.609	2.609
Superior/Temporal 1	12	1.787	5.004	2.912	8.153	2.567	4.181
Superior/Temporal 2	12	2.363	6.616	2.363	6.616	2.681	2.681
Inferior/Nasal 1	12	1.190	3.333	9.991	27.974	1.480	12.419
Inferior/Nasal 2	12	4.916	13.765	6.738	18.867	5.251	7.198
Inferior/Temporal 1	12	2.718	7.611	5.130	14.365	4.079	7.699
Inferior/Temporal 2	12	6.021	16.858	6.021	16.858	6.972	6.972
Retinal Nerve Fiber Layer Thickness (µm)							
Superior	12	5.568	15.591	5.568	15.591	6.629	6.629
Temporal	12	4.964	13.899	5.781	16.185	9.405	10.953
Inferior	12	6.039	16.910	6.039	16.910	7.531	7.531
Nasal	12	11.609	32.506	16.631	46.568	17.769	25.456
Total Mean	12	3.972	11.122	6.370	17.837	5.586	8.958
Optic Disc							
C/D Horizontal	12	0.056	0.158	0.056	0.158	6.925	6.925
C/D Vertical	12	0.031	0.087	0.031	0.087	4.039	4.039
Disc Area (mm^2)	12	0.096	0.269	0.277	0.775	4.505	12.971
Cup Area (mm^2)	12	0.114	0.318	0.114	0.318	8.409	8.409

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All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

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Table 10: RS-3000 with Follow-up On: Repeatability and Reproducibility in Measuring G-Chart Thickness, RNFL and Optic Disc
Subjects With Glaucoma

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
G Chart Thickness (µm)							
Superior/Nasal 1	12	1.624	4.549	10.121	28.338	1.868	11.640
Superior/Nasal 2	12	6.886	19.281	8.994	25.183	6.999	9.141
Superior/Temporal 1	12	1.691	4.736	1.691	4.736	2.423	2.423
Superior/Temporal 2	12	2.427	6.795	2.427	6.795	2.739	2.739
Inferior/Nasal 1	12	1.225	3.429	10.620	29.736	1.508	13.080
Inferior/Nasal 2	12	4.173	11.685	6.041	16.916	4.429	6.412
Inferior/Temporal 1	12	0.687	1.924	0.687	1.924	1.015	1.015
Inferior/Temporal 2	12	3.902	10.924	3.902	10.924	4.526	4.526
Retinal Nerve Fiber Layer Thickness (µm)							
Superior	12	7.416	20.766	7.416	20.766	9.020	9.020
Temporal	12	3.621	10.139	3.621	10.139	7.386	7.386
Inferior	12	6.654	18.632	7.337	20.543	8.648	9.535
Nasal	12	5.972	16.722	18.775	52.570	9.534	29.973
Total Mean	12	2.687	7.525	6.364	17.820	3.934	9.318
Optic Disc							
C/D Horizontal	12	0.047	0.132	0.047	0.132	5.849	5.849
C/D Vertical	12	0.055	0.155	0.055	0.155	7.142	7.142
Disc Area (mm^2)	12	0.149	0.417	0.328	0.918	7.136	15.717
Cup Area (mm^2)	12	0.151	0.422	0.151	0.422	11.323	11.323

All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

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Table 11: RS-3000 with Follow-up Off: Repeatability and Reproducibility in Measuring Central Corneal Thickness
Subjects With Corneal Disease

		Repeatability		Reproducibility		CV%	
	n	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
Central Corneal Thickness (µm)							
	12	6.762	18.933	20.669	57.874	1.283	3.922

All statistics are estimated from a nested ANOVA model with random effects operator/device and eyes within operator/device using all accepted scans.
n = Number of eyes
Repeatability SD = Square root of the residual variance
Reproducibility SD = Square root of the sum of the operator/device variance and the residual variance
CV% = Coefficient of variation in % = SD/Intercept x 100%, SD is either the repeatability SD or the reproducibility SD
Repeatability limit = 2.8 x Repeatability SD
Reproducibility limit = 2.8 x Reproducibility SD

Program: RR.sas (11DEC2012 20:58:33)

CONCLUSIONS

In summary, Nidek Co., Ltd., is of the opinion that the Nidek Optical Coherence Tomography RS-3000, with Image Filing Software NAVIS-EX, does not introduce any new potential safety risks, are as effective, and perform as well as the predicate device(s).

WARNING: Clinical studies indicate that measurements of retinal layer thickness [or central corneal thickness] performed by the RS-3000 sometimes differs from those of OCT devices made by other manufacturers, due to differences in segmentation software. Measurements made on different devices are not interchangeable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Nidek Co., Ltd.
% Ms. Lena Sattler
Orasi Consulting, LLC.
1667 Ridgewood Rd.
Wadsworth, OH 44281

MAR 15 2013

Re: K121622
Trade/Device Name: RS-3000
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC Powered
Regulatory Class: Class II
Product Code: OBO
Dated: March 4, 2013
Received: March 7, 2013

Dear Ms. Sattler:

This letter corrects our substantially equivalent letter of March 14, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT: RS-3000

510(k) Number (if known): K121622

Device Name: RS-3000

Indications for Use:

The Nidek Optical Coherence Tomography RS-3000 including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

- the retina, retinal nerve fiber layer, and optic disc, and
- the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),

as an aid in the diagnosis and management of adults having or suspected of having ocular disease.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles Chiang
2013.03.14 13:56:57 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121622